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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,331	12/28/2001	George Y. Daniloff	2232-163	6078
6449	7590	05/26/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,331

Applicant(s)

DANILOFF ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/05/04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction of species of claims 9 and 23 set forth in the previous office action has been withdrawn and the claims have been reviewed on their merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 5 "exposing" is vague. Is the sample physically contacted by the indicator system or is the sample placed near the indicator system?

Claim 1, line 6 the recitation "capable of" is vague and indefinite. The recitation "capable of" is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. See deficiencies throughout the claims.

Claim 1, line 13 the recitation "optionally" is not a positive recitation and renders the claim indefinite. Furthermore, it is unclear how detection can be performed if the ligand element does not comprise a label.

Claim 1, line 16 "the recognition element" is vague and indefinite. Is it referring to the first recognition element or the second recognition element?

Claim 1, line 16 "the portion" is vague. It is unclear what relationship exists between the portion of the indicator system and the indicator system. Alternatively the recitation "the portion" lacks clear antecedent basis.

Claim 1, line 24 the recitation "exposed" is vague. Does the indicator system come in contact with the analyte or does it come within close proximity of the analyte? Please clarify. See also deficiency found in claim 17.

Claim 20 is vague and indefinite because it is unclear how the indicator system is associated with an implantable device. Is it bound to an implantable device or is it contained within the device? Please clarify.

Claim 23 is vague and indefinite because it is unclear what the residue of the compound is. Further, it is unclear what relationship the residue of the compound has in relation to the indicator system. Does the residue bind a recognition element or the ligand element or does the residue serve some other function? It is unclear what structural and functional relationship exists between the residue of the compound and the indicator system.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 10, 11, 17, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al (US 5,503,770).

James et al disclose a method for detecting saccharides such as glucose (polyhydroxyl analyte) (col 5, lines 45-47). James et al disclose adding a compound (indicator system) to a sample and photoscopically determining a change in fluorescence due to the binding of the compound with glucose (col 3, lines 37-40). James et al disclose that the compound comprises two boronic acid moieties (first and second recognition elements) which covalently bind to glucose. James et al further disclose that the indicator system comprises a fluorophore (detection system). James et al disclose that this fluorophore does not emit fluorescence in the absence of glucose because the fluorescence of the fluorophore is quenched by the unshared electron pair of the nitrogen atom. James et al disclose that this compound can be supported on a supporting material (col 3, lines 41-46). James et al disclose that the detection can be made in situ by utilizing an optical fiber having the compound of the present invention coated on the tip (col 5, lines 56-62).

Examiner has interpreted the claims to read as a first recognition element AND a second recognition element OR a ligand element.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5-9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al in view of Colvin et al (US 6,344,360).

See above for teachings of James et al.

James et al differ from the instant invention in failing to disclose having a ligand element. James et al also fails to specifically disclose the solid support is a polymeric matrix.

Colvin et al disclose an indicator molecule for detecting the presence or concentration of glucose. Colvin et al disclose that this molecule contains a ligand element which binds to a recognition element. Colvin et al disclose that this ligand element can be an aromatic diol such as catechol (col 5, lines 1-65). Colvin et al disclose that the use of such ligands offers the advantage of being able to detect an analyte, such as glucose utilizing a fluorescent indicator molecule having a fluorescent lifetime of sufficient length, as well as having a long Stoke's shift, thereby decreasing the effect of any background noise and other interference (col 6, lines 25-35).

It would have been obvious to one of ordinary skill in the art to incorporate the use of ligand elements as taught by Colvin et al into the method of James et al because Colvin et al shows that the use of such ligands offers the advantage of being able to detect an analyte, such as glucose utilizing a fluorescent indicator molecule having a fluorescent lifetime of sufficient length, as well as having a long Stoke's shift, thereby decreasing the effect of any background noise and other interference.

With respect to the ligand capable of forming an ester bond with the recognition element. By reciting "capable of", the ligand element does not require the moiety to form an ester bond with the recognition element. Further, since Colvin et al disclose the

same aromatic diol (catechol) as disclosed in the specification on page 7, lines 5-7. The ligand element is capable of forming an ester bond.

With respect to the solid support being a polymeric matrix. James et al discloses that the compound can be immobilized on a support matrix. It is very well known in the art to use polymeric matrixes as solid supports and therefore it would have been obvious to one of ordinary skill in the art to use a polymeric matrix as a solid support.

3. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al in view of Chick et al (US 6,040,194).

See above for teachings of James et al.

James et al differ from the instant invention in failing to teach a labeled ligand element.

Chick et al disclose a method of detecting glucose in a sample. Chick et al disclose the use of analyte analogues (ligand element) which bind to macromolecules (recognition element). Chick et al disclose that the analyte analogues can be labeled with a fluorophore. Chick et al disclose that these analyte analogues (ligand element) are displaced in the presence of the analyte (glucose) (col 9, lines 20-58). Chick et al show that the use of such ligand elements allows for the detecting of glucose and also provides for sensors that are reliable, reusable and easy to use (col 2).

It would have been obvious to one of ordinary skill in the art to incorporate ligand elements as taught by Chick et al into the method of James et al because Chick et al

show that the use of such ligand elements allows for the detecting of glucose and also provides for sensors that are reliable, reusable and easy to use.

4. Claims 15, 16, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al in view of Arimori et al (US 6,387,672).

See above for teachings of James et al.

James et al differ from the instant invention in failing to specifically disclose the sample is a physiological fluid and further fails to teach the temperatures at which the measuring step takes place.

Arimori et al disclose determining glucose concentrations of a blood sample. Arimori et al disclose that determination of glucose in this type of sample is particularly important in clinical settings in order to monitor treatment of diabetes and hypoglycemia (col 1, lines 59-62).

It would have been obvious to one of ordinary skill in the art to substitute a blood sample as taught by Arimori et al for the sample of James et al because Arimori et al teaches that determination of glucose in this type of sample is particularly important in clinical settings in order to monitor treatment of diabetes and hypoglycemia. Further, it is well known in the art to detect glucose levels in a physiological fluid.

With respect to the measuring step taking place at a substantially ambient temperature and at a temperature up to about 80 degrees C, as recited in the instant claims, the optimum temperature for the measuring step can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an

optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1641

Gary Counts

Gary Counts
Examiner
Art Unit 1641
May 17, 2004

Bao-Thuy L. Nguyen
BAO-THUY L. NGUYEN
PRIMARY EXAMINER
5/25/04